Section 4: 510(k) Summary

K071027

1. Name/Address of Submitter: TriboFilm Research, Inc.
   625 Hutton Street – Suite 105
   Raleigh, NC 27606

JUL 20 2007

2. Contact Person: Mr. Vinay Sakhrani
   Vice President of Technology

3. Date Summary Prepared: March 9, 2007

4. Device Name: TriboGlide™ Silicone-Free Syringes

5. Classification Name: Piston Syringe (21 CFR 880.5860)

6. Device Class: Class II (special controls)

7. Product Code: FMF

8. Predicate Devices: 17 Kendall Monoject® Piston Syringes [multiple 510(k)s] and Kendall Piston Syringe K811065

9. Device Description and Intended Use:

   The TriboGlide™ Silicone-Free Syringes are sterile and disposable (single use) standard polypropylene piston syringes without permanently attached needles. They consist of a polypropylene syringe barrel and plunger. Various syringe sizes include 0.5ml, 1ml, 3ml, 6ml, 10ml, 12ml, 60ml and 140ml. The lubricant used in the TriboGlide syringe is a fluorocarbon based non-silicone lubricant. The TriboGlide™ Silicone-Free Syringes, when combined with an appropriate gauge needle, are used to inject fluids into, and withdraw fluids from, the body.

10. Brief Description of Testing:

    The biocompatibility testing of the lubricated syringe was established based on tests in a FDA consensus standard. The sterilization cycle was validated using a FDA consensus standard to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

11. Declaration of Conformation to Applicable Standards:

    The TriboGlide syringe complies with
    a. Specific sections of ISO 7886-1, "Guidance for Sterile Hypodermic Syringe for SingleUse, Part 1: Syringe for Manual Use.

b. ISO 11137, "Requirements for the Validation and Routine Control of Radiation Sterilization of Healthcare Products".
c. ISO 594-1:1986, ISO 594-1:1986. Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain other Medical Equipment Part 1: General Requirements.
d. ISO 594-2:1998, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain other Medical Equipment Part 2: Lock Fittings.
e. ISO 10993, Biological Evaluation of Medical Devices
    i. ISO10993-1 Evaluation and Testing
    ii. ISO10993-5 Tests for Cytotoxicity
    iii. ISO10993-10 Tests for Irritation and Sensitization
    iv. ISO10993-4 Tests for Interaction with Blood
    v. ISO10993-11 Tests for Systemic Toxicity
f. FDA Guidance Document, "Guidance on the Content of Premarket Notification [510(k)] Submission for Piston Syringes", April 1993.

12. Substantial Equivalence Comparison:
The TriboGlide syringe without needle is substantially equivalent to the predicate device, Kendall Monoject® syringe as follows,
    i. Intended Uses: Both the TriboGlide™ syringe and the Monoject® syringe are Single-Use manual syringes intended for medical use to inject fluids into and withdraw fluids from the body.
    ii. Labeling: Both of their labeling include the identity of the device, quantity and the required warnings and prescription statement according to 21 CFR 880.5860.
    iii. Design and Materials: The design of both syringes is identical. Both devices are comprised of a barrel and plunger with the exception of the type of lubricant. Both syringes are sterile and pyrogen free.

13. Conclusions Drawn: TriboGlide™ Silicone Syringes are substantially equivalent to legally marketed piston syringes for the same intended use. Any difference in technological characteristics did not raise a new issue of safety or effectiveness. Where a technological characteristic difference occurred, appropriate testing was conducted to demonstrate that the TriboGlide™ Silicone-Free Syringes were at least as safe and effective as legally marketed piston syringes for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Vinay Sakhrani
Vice President of Technology
TriboFilm Research, Incorporated
625 Hutton Street, Suite 105
Raleigh, North Carolina 27606

JUL 20 2007

Re: K071027
Trade/Device Name: TriboGlide™ Lubricated Silicone-Free Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 2, 2007
Received: June 8, 2007

Dear Mr. Sakhrani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

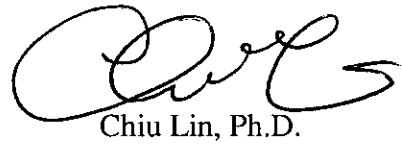
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1: Indication for Use

510(k) Number (if known): _____

Device Name: TriboGlide™ Lubricated Silicone-Free Syringe

Indication for Use: The TriboGlide™ Lubricated Silicone-Free Syringe when combined with an appropriate gauge needle is used to inject fluids into, or withdraw fluids from, the body.

Prescription Use: __X____ OR Over-the-Counter use: _____
(per 21 CFR 801.109)

Concurrence of CDRH Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091027